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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,720	07/17/2000	Martin Nicklin	MSA-021.01	7893
25181	7590	10/20/2003	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 10/20/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

FL Copy

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/617,720	NICKLIN ET AL.
	Examiner	Art Unit
	Fozia M Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 25 July 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 12 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 27, 28 and 30 is/are allowed. ~~allowable~~.
- 6) Claim(s) 29, 31-37 is/are rejected.
- 7) Claim(s) 12 and 26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**Detailed Office Action**

1. Receipt of Applicants' amendment and arguments filed on 25 July 2003 in Paper No.17 is acknowledged. Claims 1-11 and 13-25 have been canceled, claim 12 has been amended, and new claims 26-37 have been added. Thus claims 12 and 26-37 are pending and under consideration.
2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.17, 07/25/03:
  - (I) All the rejections and objections against canceled claims 13-25 are moot.

***Specification:***

- 3a. The specification stands objected to for reasons of record set forth in the previous office actions, (one mailed on 12 March 2002, in Paper NO:13, and the one mailed on 25 February 2003 in Paper NO:15).

Applicants state that they are in the process of facilitating the deposit of the hIL-IL1 clone with ATCC and upon receipt of an Accession Number and deposit date will amend the specification accordingly. This objection will be withdrawn, after said amendment to the specification is filed.

***Claim Objections:***

4. Claims 12, 26 29, 32 and 33 are objected to because of the following informalities:
- 4a. Claims 12, 26 29, 32 and 33 are objected to because they recite non-elected SEQ ID No:10. In their response to the restriction requirement, filed on 01 February 2002 in Paper NO:12, Applicants elected to prosecute SEQ ID NO:1. The Examiner decided to search SEQ ID NO:1 in conjunction with each of two alternative 5' ends,

namely SEQ ID Nos: 2 and 3. Therefore, SEQ ID Nos:1, 2 and 3 were elected, and were searched and examined. SEQ ID NO:10 was never elected.

4b. Claim 26 also recites "22-23" after SEQ ID NO:10, and it is unclear whether this is a typographical error or whether 22-23 are meant to refer to SEQ ID NOs:22-23. Appropriate correction is required.

**Claim Rejections under 35 U.S.C. §112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 29, 31 are rejected under 35 U.S.C. 112, first paragraph for reasons of record set forth in the previous office actions, (one mailed on 12 March 2002, in Paper NO:13, and the one mailed on 25 February 2003 in Paper NO:15).

Applicants submit that new claims 29 and 31 recite unique limitations of nucleic acid encoding IL-1 receptor binding polypeptides, therefore, the ordinarily skilled artisan could with routine experimentation determine which nucleotide sequences fell within the claims and those which did not, by applying the specific definite criteria recited in the claims.

This argument is not found persuasive, because Applicants have only disclosed an isolated nucleic acid comprising SEQ ID NO:1, but have not disclosed an isolated nucleic acid which comprises 95% identity to SEQ ID NO:1, and encodes an IL-1 receptor binding polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan

to produce a polynucleotide having at least 95% sequence identity to SEQ ID Nos:1, that would retain the bind to an IL-1 receptor, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

Instant specification have not set forth which nucleotides to alter, without affecting the encoded polypeptide. SEQ ID NO:1 comprises 2563 bases, 5% of this is 640 bases, therefore, one of ordinary skill in the art would not know which 640 bass to later without affecting the functional integrity of the claimed nucleic acid. With respect to claim 33, Applicants have not taught which amino acids to alter with out significantly changing the binding capacity of the polypeptide of SEQ ID NO:5. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid

which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

5b. Claims 29, 31and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the office action mailed on 12 March 2002, in Paper NO:13, pages 7-9 and the office action mailed on 25 February 2003 in Paper NO:15 .

Applicants contend that these claims recite a highly defined group of nucleic acid sequences tat encode a limited group of IL-1 receptor binding proteins. Thus, Applicants submit that they have provided a clear written description that fall within the express and strict requirements of the claims. Applicants also argue that they have defined the hybridization assay under high stringency conditions and performing such hybridization would be routine to the ordinarily skilled artisan.

This argument has been fully considered, but is not deemed persuasive, because Applicants provide written description only for the nucleic acid of nucleotide sequence set forth in SEQ ID NO:1, and nucleic acid encoding the polypeptide of SEQ ID NO:5. , Therefore the written description is not commensurate in scope with claims 29, 31 and 31 which is drawn a nucleic acid comprising a sequence having at least 95% to SEQ ID Nos:1, nucleic acid which encodes a polypeptide which has at least 95% identity to SEQ ID NO:5, or an isolated nucleic acid which hybridizes to SEQ ID NO:1, 2 or 3, respectively.

With the exception of SEQ ID NO: NOs:1, 2 and 3 the skilled artisan cannot envision the detailed structure of the encompassed polypeptide or the nucleotide encoding such and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required

Therefore, it does not appear that the inventors were in possession of a nucleic acid comprising at least 95% of SEQ ID NO:1.

5c. Claim 33 recites “.....wherein said nucleic acid molecule does not consist of nucleic acid sequence of SEQ ID NO: 54-64”, however, this recitation introduces **new matter** into the claim, because, this recitation was not disclosed or described in the specification as originally filed. Instant specification describes the nucleic acids of the instant invention on pages 33-48, however a nucleic acid having the limitations “wherein said nucleic acid molecule does not consist of nucleic acid sequence of SEQ ID NO: 54-64”, was not never described there.

Thus, the limitation “.....wherein said nucleic acid molecule does not consist of nucleic acid sequence of SEQ ID NO: 54-64”, recited in claim 33 (b), do not meet the written description provision of 35 U.S.C. 112, first paragraph, because it was never disclosed or described in the specification, as such this introduces new matter into the claim.

***Claim rejections-35 U.S.C. § 112, 2nd paragraph:***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 33 is rejected as vague and indefinite, because it recites "An isolated nucleic acid sequence which hybridizes under stringent conditions to .....", however, stringent conditions is a conditional term and renders the claims indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "stringent."

Claims 34-37 are rejected under 35 U.S.C. 112, second paragraph, in so far as they depend on claim 33 for the limitations set forth directly above.

#### **Claim rejections-35 USC § 102**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32 and 33 is rejected under 35 U.S.C § 102(b) as being anticipated by Bentos et al (28 August 1998).

Bentos et al teach isolated nucleotide which comprises 485 bases. The nucleic acid disclosed by Bentos et al is identical to instant SEQ ID NO:1 from 786 to 941, (See

attached copies of the comparisons of SEQ ID NO:1 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISONS 'A').

Instant claim 33 recites "an isolated nucleic acid comprising 100 consecutive nucleotides of SEQ ID NO:1", while claim 32 is drawn to an isolated nucleic acid which hybridizes to SEQ ID NO:1.

Therefore, the isolated nucleotide disclosed by Bentos et al meets the limitations recited in instant claims 33 (a), since it comprises 100 consecutive nucleotides of SEQ ID NO:1. It also meets the limitation recited in claim 32, because it would be expected to hybridize to instant nucleotide of SEQ ID NO:1. Therefore, Bentos et al reference anticipates the instant claims 32 and 33 in the absence of any evidence to the contrary.

### **Claim rejections-35 USC § 102**

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8b. Claims 32-37 are rejected under 35 U.S.C § 102(e) as being anticipated by Ford et al (U.S Patent 6,294,655). (SEQ ID NO:8 of U.S Patent 6,294,655, was disclosed in parent Application Number 09/287,210 filed on 05 April 1999, thus the effective filing date of U.S Patent 6,294,655 is 05 April 1999 ).

Ford et al teach an isolated nucleotide encoding Interleukin-1 Receptor Antagonists, said nucleic acids which comprise a label, expression vectors containing

said nucleotides, host cells comprising said vectors, method of making the encoded polypeptides and methods of using said polypeptides, (see abstract and column 3, line 3 through column 5, line 3 and column 9, 1-4). The nucleotide disclosed by Ford et al shares 86.6% sequence similarity to the instantly claimed nucleotide of SEQ ID NO:1; (See attached copies of the comparisons of SEQ ID NO:1 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISONS 'B").

Instant claims 32-37 are drawn to an isolated human nucleic acid comprising 100 consecutive nucleotides of SEQ ID NO:1, or which hybridizes to nucleotide of SEQ ID NO:1, or SEQ ID NO:3, and one of these nucleic acids which further comprises a label. The nucleotide disclosed by Ford et al meets "the 100 consecutive nucleotides of SEQ ID NO:1" limitation recited in instant claim 33(a), and the limitations recited in claims 34-37. It would also be expected to hybridize to nucleotide of SEQ ID NO:1, SEQ ID NO:3. Therefore, Ford's et al reference anticipates the instant claims 12, 14-16, 18-21 and 24 in the absence of any evidence to the contrary.

**Conclusion:**

9. Claims 27, 28, 30 are allowable.

**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1647

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
06 October 2003



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